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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,667	10/30/2000	Jean-Pierre Perreault	258/235	8852
34026	7590	06/16/2004	EXAMINER	
JONES DAY			ZARA, JANE J	
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LOS ANGELES, CA 90013-1025			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

3.11

**Office Action Summary**

Application No.

09/699,667

Applicant(s)

PERREAULT ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office action is in response to the communication filed 3-22-04.

Claims 1-19 are pending in the instant application.

### ***Election/Restrictions***

Applicant's election with traverse of nucleic acid encoding a ribozyme comprising a P4 region comprising the sequence 5'-GCAUGG-3' in the reply filed on 3-22-04 is acknowledged. The traversal is on the ground(s) that the claimed invention, including the 6 different sequences pertaining to the P4 region (e.g. in claim 11), are all related to an enzyme having certain structures defined by certain physical and chemical characteristics. Applicants assert further that even if the restriction requirement is necessitated by having nucleotides encoding for different enzymes, the Commissioner allows examination of up to ten sequences as a reasonable number for examination purposes. This is not found persuasive because the different nucleotide sequences encoding the P4 region constitute chemically different and distinct inventions, each requiring a separate search of the existing data bases. Proper examination of each of these different and distinct inventions therefore requires a separate search for each of the different enzymes claimed.

The requirement is still deemed proper and is therefore made FINAL.

The sequences other than 5'-GCAUGG-3' encoding the P4 region are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected

invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3-22-04.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 8. 10. 12. 17 and 18, it is unclear what "bottom end" means. The position of nucleotides (e.g. in relation to the 5' or 3' terminal of the ribozyme structure) cannot be determined from this term. Appropriate clarification is requested.

In claims 2-6, line 2, it is unclear what "bottom end" means. The position of nucleotides (e.g. in relation to the 5' or 3' terminal of the ribozyme structure) cannot be determined from this term. Appropriate clarification is requested.

The metes and bounds of claim 18 cannot be determined because in claim 18, lines 14-16 9 (i.e. in (iii) of claim 18) it is unclear what is meant by "the fourth nucleotide 3' to the cleavage site is capable of forming a triplet with the enzyme comprising a non-conventional Watson-Crick base pair and a conventional Watson-Crick base pair." (e.g. Does this mean that hydrogen bonding will not be involved in the triplet formation, or are there non-conventional bases replacing the regular bases normally involved in conventional Watson-Crick base pairing?) Appropriate clarification is required.

In claim 19 lines 1 and 2, it is unclear what "H' and a nucleotide immediately 5' to it" means. "H" was not defined in this or any other claims. Appropriate clarification is requested.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to compositions and methods comprising a nucleic acid enzyme which comprises a substrate binding portion base paired to six nucleotides 3' to the substrate cleavage site with the 3'-most first position defined as a uracil, and the remaining 5 nucleotides being variable; a P3 region capped by a loop L3 of seven or less nucleotides; a P2 region bound covalently to the rest of the ribozyme and comprising a double stranded portion with three base pairs of G-C; a P4 region comprising a homopurine base pair; a P1.1 region formed by base pairing two nucleotides between the P4 and the L3 loop; and J4/2 region five nucleotides long and bound to the P2 region and to the P4 region. The claims read on a myriad of nucleotide sequences, including nucleic acid substitutions, deletions, insertions and/or additions that may be made to the nucleic acid enzymes. The scope of the claims includes

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numerous structural variants and the genus is highly variant because a significant number of structural differences between genus members is permitted. Concise structural features that could distinguish compounds in the genus from others are missing from the disclosure. That is, no concise structural attributes (e.g. nucleotide sequences defining a nucleic acid enzyme) that could distinguish the claimed compounds in the genus from others are provided in the claims. The instant disclosure and the art teach various trans-acting  $\delta$  ribozymes and complementary substrates (e.g. see figure 1 and Table II of J. Biol. Chem. 273(21): 13,182-13,188, 1998). Since the instant claims and disclosure fail to describe the characteristics concisely identifying members of the proposed and very broad genus, and because the genus is highly variant, the description provided for the claimed genus is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the very broad genus claimed. Thus, Applicant was not in possession of the claimed genus.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

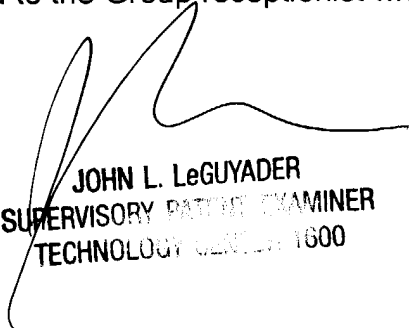
Claims 1-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Ananvoranich et al.

Ananvoranich et al teach compositions and methods comprising a nucleic acid enzyme which comprises a substrate binding portion base paired to six nucleotides 3' to the substrate cleavage site with the 3'-most first position defined as a uracil, and the remaining 5 nucleotides being variable; a P3 region comprising a double stranded portion which comprises 3'U-A5' capped by a loop L3 of seven or fewer nucleotides; a P2 region comprising a double stranded portion with three base pairs of G-C, and bound covalently to the rest of the ribozyme; a P4 region wherein the first base pair at the bottom end is a homopurine base pair, and wherein the double stranded portion of the P4 region comprises 5'-GCAUGG-3'; a P1.1 region formed by base pairing two GC base pairs between the P4 and the L3 loop; and J4/2 region bound to the P2 region and to the P4 region, which substrate binding portion comprises a six nucleotide sequence with its fourth position being either an adenine or guanine; and which substrate includes a seven nucleotide sequence with at least 6 nucleotides 3' to the cleavage site, and at least one nucleotide 5' to the cleavage site, wherein the first nucleotide 3' to the cleavage site is guanine and can form a wobble pair with the ribozyme, and the nucleotide 5' to the cleavage site is not a guanine or thymine; wherein the second, third, fifth and sixth nucleotide 3' to the cleavage site can form conventional Watson-Crick base pairs with the ribozyme, the fourth nucleotide 3' to the cleavage site can form a triplet with the ribozyme, and the ribonucleotide directly 5' to the cleavage site does not form a base pair with the ribozyme (See  $\delta R_z$  in figure 1, figure 2 on page 13,184, and the last paragraph on page 13,182).

### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
JOHN L. LeGUYADER  
SUPERVISORY PATENT EXAMINER  
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JZ  
6-9-04